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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,489	02/15/2002	Franciscus Antonius Maria Rijsewijk	454313-2280.1	5246

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EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/077,489	Applicant(s) Rijsewijk
	Examiner Anne Marie Wehbé	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 6, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *16-62, 64-66, and 68-107* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16-62, 64-66, and 68-107* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *09/232,469*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendment and response received on 1/6/03 has been entered. Claims 63 and 67 have been canceled, and new claims 68-107 have been entered. Claims 16-62, 64-66, and 68-107 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Priority

Applicant's amendment to the specification to reflect the status of this application as a continuation-in-part of parent application 09/232,469, rather than a divisional application, and the correction of the filing date of the 9609402 document is acknowledged. Applicant's statement that the certified copy of the foreign priority document was submitted in parent case 09/232,469 is also acknowledged.

Claim Rejections - 35 USC § 101

The rejection of claims 16-67 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-80 of U.S. Patent No. 6,451,770 (9/17/02),

hereafter referred to as the '770 patent, stands over pending claims 16-62, 64-66, and 68-107. The applicant has not provided any arguments which traverse the instant grounds of rejection. Therefore, the rejection of record is maintained.

Applicant's statement that a terminal disclaimer will be filed upon identification of allowable subject matter is acknowledged.

Claim Rejections - 35 USC § 112

The rejection of claims 16-67 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained in part over claims 16-62, and 64-66. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the following instant grounds of rejection for reasons of record as discussed in detail below.

In view of applicant's arguments, supporting references and data, the scope of enablement has been modified as follows: the specification, while being enabling for an immunogenic composition comprising a plasmid encoding an immunogen from a bovine pathogen operatively linked to a **viral** promoter and a liquid jet intradermal administration apparatus that administers the composition to a bovine without a needle into the dermis, epidermis and/or hypodermis and methods of inducing an immunological response or vaccinating against a bovine pathogen comprising the administration of a encoding an immunogen from a bovine pathogen operatively linked to a **viral** promoter using a liquid jet intradermal administration apparatus that administers

the composition to a bovine without a needle into the dermis, epidermis and/or hypodermis, does not reasonably provide enablement for methods of immunizing or vaccinating a bovine against a bovine pathogen comprising administering a plasmid encoding a bovine pathogen immunogen operatively linked to any promoter using a liquid jet intradermal administration apparatus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In regards to the remaining grounds of rejection, i.e. the choice of promoter, the applicant argues that Bohm et al., cited by the office, concerns intramuscular injection of plasmid DNA rather than the injection-free intradermal administration as taught by applicants. The applicant also cites Donnelly et al. as evidence that the use of strong enhancer/promoters, such as CMV IE, SV40 early promoter and RSV LTR, for plasmid vaccination was known at the time of filing. The applicant also cites Verma et al. for teaching that it is preferable to use strong promoters rather than weak promoters. In response, it is noted that both Donnelly and Verma are post-filing references. Furthermore, both Donnelly and Verma clearly teach the use of strong viral promoters. As noted in the previous office action, the specification does not provide sufficient guidance for the use of any promoter to drive the expression of a bovine pathogen immunogen in the instant invention. The specification discloses the use of the CMV promoter; it does not disclose the identity or characteristics of other promoters useful for the instant invention. Further, the specification's working examples and supporting data provided with the instant response all utilize the CMV promoter. The specification does not teach the level of expression or types of

antigen presenting required to generate the high titer anti-G protein antibody response observed after Pigjet administration of plasmid encoding G protein operatively linked to CMV promoter. While the specification suggests that dendritic cells present in the skin are the intended target of the vaccination, it does not teach dendritic cell specific promoters or demonstrate that in fact dendritic cells are transfected using the Pigjet. Thus, in view of the high level of variability between promoters as taught by Verma et al. and Bohm et al., the breadth of the claims, the lack of guidance provided by the specification, and the teachings of the art at or around the time of filing to use strong viral promoters, it would have required undue experimentation to use non-viral promoters, to express BRSV G proteins in the dermis using the instant methodology.

The applicant has also argued that working examples are not required to meet the requirements for enablement under 35 U.S.C. 112, first paragraph, citing *In re Anderson, In re Obukowitz,* and *In re Angstadt and Griffen.* In response, the office agrees with applicant's citation of *In re Borkowski,* the issue in determining enablement is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. Based on the analysis presented in the previous office action and discussed in detail above, the office has concluded that it would have required undue experimentation to use non-viral promoters to express bovine pathogen immunogens in the dermis using the instant methodology. Furthermore, please note that the office has analyzed the specification for compliance with the requirements of 35 U.S.C. 112 , first paragraph, in direct accordance to the factors outlined in *In re Wands*, namely 1) the nature of the invention, 2) the state of the prior art, 3) the predictability of the art, 4) the amount of

direction or guidance present, 5) the breadth of the claims, and 6) the presence or absence of working examples, and presented detailed scientific reasons and evidence in the form of printed publications for the finding of a lack of enablement in the instant application. It is also noted that case law including the Marzocchi decision sanctions both the use of sound scientific reasoning and printed publications to support a holding of non-enablement (see *In re Marzocchi* 169 USPQ 367, and *Ex parte Sudilovsky* 21 USPQ2d 1702). 35 U.S.C. § 112 further requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). Ultimately, ".. the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." *In re Gardner* 166 USPQ 138 (CCPA) 1970.

The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendment to the claim..

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to

expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER